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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Hong Jin *et al.*	Confirmation No.: 8169
Application No.: 09/724,388	Group Art Unit: 1648
Filed: November 28, 2000	Examiner: Lucas, Zachariah
For: RECOMBINANT RSV EXPRESSION SYSTEMS AND VACCINES	Attorney Docket No.: 7682-051-999

SUPPLEMENTAL RESPONSE AND STATEMENT OF SUBSTANCE OF INTERVIEW

Commissioner for Patents
P.O. BOX 1450
Alexandria, Virginia 22313-1450

Sir:

Further to applicants' Amendment under 37 C.F.R. § 1.111 filed on June 28, 2005, which was submitted in response to the non-final Office Action mailed on December 28, 2004, and to the Examiner Interview conducted on September 13, 2005, and in response to the Office Communication dated September 15, 2005, Applicants hereby submit (a) a Supplemental Response and Statement of Substance of Interview; and (b) an executed Declaration of Richard R. Spaete under 37 C.F.R. § 1.132, accompanied by (i) Exhibit A: Curriculum Vitae of Dr. Richard R. Spaete; (ii) Alphabetical List of References Cited; and (iii) Copies of References Cited.

The applicants take this opportunity to thank Group Director Elliott and Interference Specialist Caputa for their participation in the interview with Examiner Lucas and Supervisory Examiner Housel on September 13, 2005,[1] and for the courtesies extended by the United States Patent and Trademark Office ("USPTO") participants during the interview.

Summary of Interview begins at page 3 of this paper.

Remarks begin at page 4 of this paper.

[1] The Office Action dated December 28, 2004 found claims copied from U.S. Patent No. 6,033,886 to Conzelmann (the "Conzelmann '886 patent") to be unpatentable based on grounds (under 35 U.S.C. § 112, first paragraph) also applicable to the Conzelmann '886 patent; thus, requiring Group Director approval. MPEP § 1003 ¶ 6; § 2307.02.

1. SUMMARY OF INTERVIEW

During the interview, enablement of *vaccine* claims was discussed. As the applicants understand it, the USPTO requires vaccines to have "protective" efficacy -- *i.e.*, prevent infection.[2] The applicants' expert, Dr. Spaete explained, however, that not all vaccines prevent infection -- this is especially true in the paramyxoviruses such as RSV and PIV, where the goal of a vaccine is to induce an immune response that ameliorates the symptoms of infection. The applicants explained how the teachings of the specification enabled this real-world standard for vaccines.

Regardless of the enablement standard for vaccines, the applicants stressed that the "vaccine standard" should not be applied to claims covering the genetically engineered viruses, *i.e.*, claims 7 and 18, which have utility independent of vaccines; i.e., the engineered viruses could be used as expression vectors for the production of proteins, including viral antigens that can be used in diagnostic kits and/or for antibody production. "[W]hen a . . . composition claim is not limited by a recited use, any enabled use . . . is sufficient to preclude a rejection for nonenablement based on how to use." M.P.E.P. § 2164.01(c).

With respect to enablement of the virus claims, the USPTO requested an analysis of the guidance provided in the specification that enables the skilled artisan to reliably make genetically manipulated viruses that are infectious and replication competent. Recognizing that the specification describes and demonstrates by way of working examples the successful engineering of a variety of mutations into the viral genome, the USPTO requested an analysis of how the guidance and working examples lend support for the insertion and deletion mutants covered by

[2] During the interview, the applicants pointed out the discrepancy in the standard applied by the PTO to pending claim 12 versus issued claim 12 of the Conzelmann '886 patent. The Conzelmann '886 patent claims vaccines, yet has no better support for "protection" than applicants.